

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

I. Claim Amendments

Claims 24-37 were pending in this application when examined.

Claim 24 has been amended to recite that the first solution and the second solution each contain “dipotassium hydrogen phosphate” from claim 26, and to recite that the second solution contains “at least one amino acid selected from the group consisting of L-leucine, L-isoleucine, L-valine, L-lysine hydrochloride, L-threonine, L-tryptophan, L-methionine, L-phenylalanine, L-cysteine, L-tyrosine, L-arginine, L-histidine, L-alanine, L-proline, L-serine, glycine, L-aspartic acid and L-glutamic acid” from claim 27. As a result, claims 26 and 27 have been cancelled.

In addition, claim 24 has been amended to recite that the first solution contains “glucose, sodium chloride, sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate”. Support for this amendment can be found on page 21, lines 7-9 of the originally filed specification.

Claim 31 has been amended to recite that the first solution and the second solution each contain “sodium chloride” from claim 33, and to recite that the second solution contains “sodium hydrogen carbonate” from claim 34. As a result, claims 33 and 34 have been cancelled. In addition, claim 31 has been amended to recite that the first solution contains “glucose, calcium chloride and magnesium chloride”, and that the second solution also contains “sodium hydrogen carbonate”, “potassium dihydrogen phosphate” and “potassium chloride”. Support for these amendments can be found on page 17, lines 19-26 of the originally filed specification.

As a result of the above-discussed amendments, claims 25-29 and 32-36 have been cancelled without prejudice or disclaimer.

II. Information Disclosure Statement

The Examiner considered the Information Disclosure Statement (IDS) filed on February 22, 2010. However, the Examiner did not initial the Yoshitoshi et al. reference cited on the SB/08 form (reference CA). Applicants enclose herewith modified version of the SB/08 form originally filed on February 22, 2010, and respectfully request the Examiner to consider the Yoshitoshi et al. reference, and return an initialed copy of the SB/08 form to Applicants’ attorney.

III. Claim Rejections Under 35 U.S.C. § 103

A. Segers in view of Veech

The Examiner rejects claims 24, 25, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (U.S. 5,383,324) (hereinafter, “Segers”) in view of Veech (U.S. 4,663,166). As applied to the amended claims, Applicants respectfully traverse the rejection.

1. The Features of Claim 24

Claim 24 recites the following features:

- (i) a first solution containing dipotassium hydrogen phosphate, glucose, sodium chloride, sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate in a first chamber;
- (ii) a second solution containing dipotassium hydrogen phosphate and at least one amino acid selected from the group consisting of L-leucine, L-isoleucine, L-valine, L-lysine hydrochloride, L-threonine, L-tryptophan, L-methionine, L-phenylalanine, L-cysteine, L-tyrosine, L-arginine, L-histidine, L-alanine, L-proline, L-serine, glycine, L-aspartic acid and L-glutamic acid in a second chamber; and
- (iii) the first solution and the second solution each have a potassium ion concentration of about 13 to 35 mEq/L.

2. Segers

Segers does not disclose or suggest **sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate**, or the specific combination thereof in a first solution in a first chamber. Thus, Segers does not disclose or suggest feature (i) “a first solution containing dipotassium hydrogen phosphate, glucose, sodium chloride, sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate in a first chamber”, as recited in claim 24.

Furthermore, Segers provides no reason or motivation to those skilled in the art to prepare a solution containing sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate in combination with dipotassium hydrogen phosphate, glucose and sodium chloride in a first chamber.

Therefore, those skilled in the art would not have arrived at feature (i) of claim 24 from Segers.

3. Veech

Veech discloses in column 35, Table III, an electrolyte solution containing sigma l-lactate⁻. The reference further discloses that “Optionally, solutions of this invention as shown in Table III can additionally contain...(b)...sigma inorganic sulfate” (see column 35, lines 53 to 60, in particular lines 59-60).

However, the reference does not explicitly disclose **sodium lactate, magnesium sulfate and zinc sulfate, or calcium gluconate**.

Thus, Veech does not disclose or suggest feature (i) of claim 24, and therefore does not cure the deficiencies of Segers.

4. The Non-obviousness of Claim 24

In view of the above, one of ordinary skill in the art would not have arrived at feature (i) of “a first solution containing dipotassium hydrogen phosphate, glucose, sodium chloride, **sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate** in a first chamber”, or the specific combination of features (i), (ii) and (iii) of claim 24, from the disclosures of Segers and Veech.

Therefore, claim 24 would not have been obvious over Segers in view of Veech.

B. Segers in view Veech, and further in view of Nakamura

The Examiner rejects claims 27 and 30 under 35 U.S.C. 103(a) as being unpatentable over Segers in view of Veech, as applied to claims 24, 25, 28 and 29 above, and further in view of Nakamura et al. (U.S. 6,867,193) (hereinafter, “Nakamura”). Claim 27 has been cancelled. As applied to claim 30, Applicants respectfully traverse the rejection.

The arguments above regarding Segers and Veech are also applicable to this rejection. Thus, Segers and Veech do not disclose or suggest “a first solution containing dipotassium hydrogen phosphate, glucose, sodium chloride, **sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate** in a first chamber” (feature (i) of claim 24), or the specific combination of features (i), (ii) and (iii) of claim 24. Nakamura does not cure these deficiencies.

The Examiner applied Nakamura for teaching amino acids. However, the reference does not disclose or suggest a first solution containing “dipotassium hydrogen phosphate”, “sodium lactate”, “calcium gluconate”, “magnesium sulfate” and “zinc sulfate”, in a first chamber, as recited in feature (i) of claim 24.

Moreover, the reference does not disclose or suggest a second solution containing “potassium dihydrogen phosphate” along with at least one amino acid in a second chamber. Thus, the reference does not disclose or suggest feature (ii) of claim 24.

Accordingly, claim 24 would not have been obvious over Segers in view of Veech, and in further view of Nakamura.

Claim 30 depends from claim 24, and thus also would not have been obvious over the references.

C. Segers in view Veech, and further in view of Stone

The Examiner rejects claim 26 under 35 U.S.C. 103(a) as being unpatentable over Segers et al. in view of Veech, as applied to claims 24, 25, 28 and 29 above, and further in view of Stone et al. (U.S. 4,489,097) (hereinafter, “Stone”). Claim 26 has been cancelled, rendering its rejection moot. However, as applied to claim 24, Applicants respectfully traverse the rejection.

The arguments above regarding Segers and Veech are also applicable to this rejection. Thus, Segers and Veech do not disclose or suggest “a first solution containing dipotassium hydrogen phosphate, glucose, sodium chloride, **sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate** in a first chamber” (feature (i) of claim 24), or the specific combination of features (i), (ii) and (iii) of claim 24. Stone does not cure these deficiencies.

The Examiner cites Stone for disclosing dipotassium hydrogen phosphate.

However, Stone does not disclose or suggest a first solution containing “glucose, sodium chloride, **sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate** in a first chamber”, as recited in feature (i) of claim 24.

Accordingly, claim 24 would not have been obvious over Segers in view of Veech, and in further view of Stone.

D. Segers in view of Nakamura

The Examiner rejects claims 31-37 under 35 U.S.C. 103(a) as being unpatentable over Segers in view of Nakamura. As applied to the amended claims, Applicants respectfully traverse the rejection.

1. The Features of Claim 31

Claim 31 recites the following features:

(i) a first solution containing sodium chloride, glucose, calcium chloride and magnesium chloride in a first chamber;

(ii) a second solution containing sodium chloride, sodium hydrogen carbonate, potassium dihydrogen phosphate and potassium chloride in a second chamber; and

(iii) the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline.

2. Segers

Segers does not disclose or suggest potassium dihydrogen phosphate. Accordingly, the reference fails to disclose or suggest feature (ii) of claim 31 of “a second solution containing sodium chloride, sodium hydrogen carbonate, **potassium dihydrogen phosphate** and potassium chloride in a second chamber”.

Furthermore, Segers provides no reason or motivation to those of ordinary skill in the art to prepare a solution containing potassium dihydrogen phosphate in combination with sodium chloride, sodium hydrogen carbonate and potassium chloride.

Therefore, one of ordinary skill in the art would not have arrived at feature (ii) of claim 31 from the reference.

In addition, the Examiner admits that Segers does not disclose that the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline, as recited in claim 31 (see Office Action, page 13, lines 4-6).

Accordingly, the reference fails to disclose or suggest features (ii) and (iii) of claim 31.

3. Nakamura

The Examiner applied Nakamura for disclosing an osmotic pressure ratio between an amino acid and an albumin containing solution of 2.8-3.3 (see Office Action, page 13, lines 7-11).

4. Osmotic Pressure

The Examiner asserts that “An ordinary skilled artisan would have been motivated to adjust the osmotic pressure of the solutions because the osmolality of medicinal preparations is important for the safety and efficacy of the preparation” (see page 13, lines 17-20).

However, Nakamura discloses that “the albumin preparation of the present invention is considered to have excellent effect in treatment against failure of the liver functions including hepatic encephalopathy, hepatic coma and the like” (see column 9, lines 44-47). Accordingly, Nakamura’s preparation, having an osmotic pressure of 2.8-3.3, is sufficiently safe for a patient. One of ordinary skill in the art would not have had any reason or rationale to further adjust the

osmotic pressure ratio of the preparation to “about 1 relative to physiological saline”, as recited in claim 31, from the teachings of Nakamura, because the range of 2.8-3.3 is sufficiently safe for a patient. Thus, the Examiner’s assertion that one of ordinary skill in the art would have been motivated to adjust the osmotic pressure of the solutions is clearly based upon the Applicants’ own disclosure, which is impermissible hindsight reasoning.

Accordingly, one of ordinary skill in the art would not have arrived at feature (iii) of claim 31 from Nakamura.

5. The Non-obviousness of Claims 31 and 37

One of ordinary skill in the art would not have arrived at feature (ii) of claim 31 of “a second solution containing sodium chloride, sodium hydrogen carbonate, **potassium dihydrogen phosphate** and potassium chloride in a second chamber”, feature (iii) of claim 31 of “the first solution and the second solution each have **an osmotic pressure ratio of about 1** relative to physiological saline”, and the specific combination of features (i), (ii) and (iii) of claim 31, from Segers and Nakamura.

Therefore, claim 31 would not have been obvious over Segers in view of Nakamura.

Claim 37 depends from claim 31, and thus also would not have been obvious over the references.

IV. Conclusion

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejections set forth by the Examiner have been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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